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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,980	09/05/2003	Stanten C. Spear	P0011669.00	8939

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EXAMINER	
LAMPRECHT, JOEL	
ART UNIT	PAPER NUMBER
3737	

MAIL DATE	DELIVERY MODE
04/18/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/655,980	SPEAR ET AL.	
	Examiner	Art Unit	
	JOEL M. LAMPRECHT	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5, 7-12, 16-17, 20, 22-28, 31, 36, and 38-41 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosenman et al (US 6,004,269). Rosenman et al. disclose a catheter drug delivery system used for locating a target site for delivering therapy to a patient comprising advancing a delivery device with steerable portion and deflectable portion which tapers for delivery of drugs to a first site through a lumen (also dual lumen forms) in fluid communication with a thru lumen and delivering contrast media from the distal end of the delivery device within the first site (Fig 8-10, Col9 Line 38-Col 10 Line 24). Additionally Rosenman et al. disclose advancing a guidewire within a patient and advancing the delivery device (Col 3 Line 40-Col 4 Line 14) to the area along the first site via a guide catheter before advancing the delivery device to the area along the first site through and outward from the guide catheter, and later advancing the guide catheter again over the delivery device (Col 4 Line 49 - Col 5 Line 7). Also Rosenman et al. disclose a single shaft lumen with multiple lumen portions offset from each other but still in fluid communication through the use of Luer fittings (Fig 8-9, Col 8

Line 15 – Col 9 Line 4). Finally Rosenman et al. disclose advancing a guide wire outward form the distal end through the thru lumen of a delivery device within the first site and advancing the delivery device over the guide wire, and the deflectable tip includes outer wall and inner wall forming a tip lumen in fluid communication with the thru lumen and has a distal opening at the top (Col 13 Line 25-56). The delivery device has an outer diameter of les than 7 French in embodiments and tapers along its length to less than 6 French. The deflectable portion of the delivery catheter shaft has a Pebax material, which begins at 75D and becomes more deflectable towards the distal end of the delivery unit, eventually hitting 35D (Col 9 Line 19 – Col 9 Line 62). The additional form of therapy suggested by Rosenman et al consists of extending a wire through the lumen of the catheter guide system to test for penetration of the myocardium (Col 4 Line 15-50).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-43 rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenman et al. in view of Niazi (US 6,638268 B2). Rosenman et al. disclose a catheter drug delivery system used for locating a target site for delivering therapy to a patient comprising advancing a delivery device with steerable portion and deflectable portion which tapers for delivery of drugs to a first site through a lumen (also dual lumen forms) in fluid communication with a thru lumen and delivering contrast media from the distal end of the delivery device within the first site (Fig 8-10, Col9 Line 38-Col 10 Line 24). Additionally Rosenman et al. disclose advancing a guidewire within a patient and advancing the delivery device (Col 3 Line 40-Col 4 Line 14) to the area along the first site via a guide catheter before advancing the delivery device to the area along the first site through and outward from the guide catheter, and later advancing the guide catheter again over the delivery device (Col 4 Line 49 - Col 5 Line 7). Also Rosenman et al. disclose a single shaft lumen with multiple lumen portions offset from each other but still in fluid communication through the use of Luer fittings (Fig 8-9, Col 8 Line 15 – Col 9 Line 4). Finally Rosenman et al. disclose advancing a guide wire outward form the distal end through the thru lumen of a delivery device within the first site and advancing the delivery device over the guide wire, and the deflectable tip includes outer

wall and inner wall forming a tip lumen in fluid communication with the thru lumen and has a distal opening at the top (Col 13 Line 25-56). The delivery device has an outer diameter of les than 7 French in embodiments and tapers along its length to less than 6 French. The deflectable portion of the delivery catheter shaft has a Pebax material which becomes more deflectable towards the distal end of the delivery unit, eventually hitting 35D (Col 9 Line 19 – Col 9 Line 62).

Rosenman et al. do not disclose the delivery of a pacing lead to the target over the guide wire itself. Rosenman et al. additionally do not disclose a gradual taper, rather they disclose a component taper over the length of the tip region. Attention is paid to the secondary reference by Niazi which discloses a gradual taper towards the distal end of the central lumen allowing for a end diameter of 5 French and contains a tip lumen suitable for delivery of contrast media as well as disclosure of a hydrophilic guidewire system (Claim 1, Col 2 Line 15-40, Col 5 Line 29-65, Col 4 Line 15-35). Niazi also discloses the retraction of the fluid delivery system (Col 4 Line 35-55, Col 5 Line 29-60) and specifically mentions the coronary sinus vein as the target site (Claim 24). It would have been obvious to one of ordinary skill in the art at the time of the invention to have incorporated the gradual taper and pacing lead delivery system of Niazi with the contrast media delivery system of Rosenman et al as Rosenman et al disclose in Col 4 Line 15 – 50 that electrical monitoring with a wire placed at the distal tip of the catheter delivery system is an important measure of penetration of the myocardium.

Rosenman et al. do not disclose using a PEBA materical with jet milled tungsten carbide or using a non-braided section, rather they use a braided stainless steel

variation which starts and comprises the range of Applicant's Durometer ratings from 72D to 40D to 35D reading. The selection of jet milled tungsten carbide and non-braided stainless steel on the second portion is a design choice and would have been obvious to one of ordinary skill in the art at the time of the invention.

Claim 44 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenman et al US 6,004,269 in view of Leiden et al (US 6,297,220 B1). As disclosed above Rosenman et al discloses a steerable delivery device within the body and for use of locating a target site via a contras injection, but does not specifically mention the location of the coronary sinus ostium by the flow of the contrast media and by that locating advancing the device upstream into the coronary sinus. Attention is then directed to the secondary reference by Leiden et al which discloses the use of fluoroscopic-injection based guidance of a catheter into the coronary sinus ostium. It would have been obvious to one of ordinary skill in the art at the time of the invention to have used the methods of Leiden et al for the location of the coronary sinus ostium with the contrast-injection navigation methods of Rosenman et al for the purpose of treating and locating the coronary sinus ostium (Leiden et al Col 11 Line 55- Col 12 Line 20).

Response to Arguments

Applicant's arguments filed 1/09/08 have been fully considered and the only issue raised has been given careful consideration, but the arguments raised are not persuasive. Regarding the argument filed stating that Rosenman or Niazi do not

disclose the method of delivering contrast media from a distal end of a delivery device within a first sit to locate a target site the Examiner respectfully disagrees. Rosenman distinctly discloses, in the column 12 passage cited by Applicant that the contrast delivery confirms the location of a target site, which of course would be locating a target site. There is no distinction that the first site must be different from the target site within the claim being argued, nor is there a limitation that confirming the location of a target site does not constitute "locating a target site", as it appears that is exactly what is being accomplished through the methods of Rosenman cited by Applicant. Accordingly, all of Applicant's raised issue(s) have been addressed and refuted.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joel M. Lamprecht whose telephone number is (571) 272-3250. The examiner can normally be reached on Monday-Friday 7:30AM-4PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian L Casler/
Supervisory Patent Examiner, Art Unit 3737

JML